

EMC TEST REPORT

Test Report No.	WC1202311.2 Rev A	Date of issue:	20 April 2012
Product Name	Smart implant transceiver		
Model(s) Tested	51473		
Serial No(s) Tested	624955		
Product Description	909-921 MHz transceiver		
Manufacturer	Data Sciences Internationa	al	
	119 14 th Street		
	St Paul, MN 55112		
Test Result	■ Positive □ No	egative	

TÜV SÜD America Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV SÜD America Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV SÜD America Inc issued reports.

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REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	26	13 April 2012	Initial Release
А	26	20 April 2012	Page 4: Corrected EUT Power from 110 V / 60 Hz to 3.6 VDC.





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EMC TEST REGULATIONS:

The tests were performed according to the following regulations:

FCC Part 15 Subpart C Section 15.249 Paragraph (a), (d)

FCC Part 15 Subpart C Section 15.207 Paragraphs (a)

FCC Part 15 Subpart B Section 15.109

IC RSS-210 Issue 8 Section A2.9 (a), (b)

IC RSS-Gen Issue 3 Sections 4.6.1, 7.2.5

ENVIRONMENTAL CONDITIONS IN THE LAB

Actual

: 19-21°C Temperature: Atmospheric pressure : 97-99kPa Relative Humidity : 30-33%

POWER SUPPLY UTILIZED

: 3.6 VDC Power supply system

TEST EQUIPMENT

All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

MEASUREMENT UNCERTAINTY

The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system has a measurement uncertainty of ±1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. The test system has a measurement uncertainty of ±4.8 dB. All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

SIGN EXPLANATIONS

□ - not applicable

■ - applicable



Field strength of fundamental/harmonics FCC 15.249(a), IC RSS-210 A2.9(a)

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 8.2.3, 8.2.4. The implantable transmitter was tested in a body simulator.

Maximum field strength of the fundamental is 77.1 dB_μV/m (7.16 mV/m) at 915.38 MHz.

No harmonics were detected.

Test location

- - Wild River Lab Large Test Site (Open Area Test Site)
- □ Wild River Lab Small Test Site (Open Area Test Site)

Test distance

■ - 3 meters

LACT	\sim	HIN	m	nn+
Test	eu	ulu		311 1

TUV ID.	Model	Manufacturer	Description	Serial	Cal Due
WRLE03995	EM-6917B	Electro-Metrics	Biconicalog Periodic	151	06-May-12
WRLE02674	85662A	Hewlett-Packard	Analyzer Display	2050A02007	07-Dec-12
WRLE02690	8568B	Hewlett-Packard	Spectrum Analyzer	2430A00930	07-Dec-12
WRLE02681	85650A	Hewlett-Packard	Quasi-Peak Adapter	2430A00562	24-May-12
WRLE02670	8447D	Hewlett-Packard	Preamplifier	2443A03954	Code B 06-Feb-13

Test limit

Fundamental	Field strength	Field strength
Frequency	of	of harmonics
(MHz)	(MHz) fundamental	
	mV/m	
902-928	50	500

Field strength limits are specified at a distance of 3 meters. The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands above 1000 MHz. As shown in §15.35(b), for frequencies above 1000 MHz, the field strength limits in paragraphs (a) and (b) of this section are based on average limits. However, the peak field strength of any emission shall not exceed the maximum permitted average limits specified above by more than 20 dB under any condition of modulation.

Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and guasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees. The transmitter is rotated through 3 orthogonal axes to determine worst case.

Test Data, dB_μV/m

see next page



Measurement summary for limit1: FCC 15.249 902-928 <1ghz-qp 3m (Qp)						
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1	
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	FCC 15.249 902-	
		(dB)			928 <1ghz-qp 3m	
915.38 MHz	77.93 Qp	3.1 / 22.59 / 26.52 / 0.0	77.1	V / 1.25 / 305	-16.9	
909.312 MHz	76.8 Qp	3.09 / 22.45 / 26.5 / 0.0	75.84	V / 1.31 / 306	-18.16	
920.538 MHz	76.18 Qp	3.11 / 22.42 / 26.53 / 0.0	75.18	V / 1.24 / 307	-18.82	

No other signals detected up to 9.30 GHz.





Spurious Radiated Emissions 30 - 9300 MHz

FCC 15.249(d), IC RSS-210 A2.9(b)

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 8.2.3, 8.2.4.

No spurious emissions were detected within 10 dB of the limit.

Test limits

Emissions radiated outside of the specified frequency bands, except for harmonics, shall be attenuated by at least 50 dB below the level of the fundamental or to the general radiated emission limits in §15.209, whichever is the lesser attenuation.

15.209

Ī	Frequency	Field strength	Field strength	Measurement
	(MHz)	(μV/m)	(dB _µ V/m)	distance (m)
ĺ	30 - 88	100	40	3
	88 - 216	150	43.5	3
	216 - 960	200	46	3
	Above 960	500	54	3

All measurements made at 3 meters. The emission limits shown in the above tables are based on measurements employing a CISPR guasi-peak detector except for the frequency bands 9-90 kHz, 110-490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated emission measurements are specified in this part, including average emission measurements below 1000 MHz, there also is a limit on the peak level of the radio frequency emissions. Unless otherwise specified, e.g., see §§ 15.250, 15.252, 15.255, and 15.509-15.519, the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees.

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

Test distance

■ - 3 meters

Test Equipment

rest Equipme	rest Equipment							
TUV ID	Model	Manufacturer	Description	Serial	Cal Due			
WRLE03995	EM-6917B	Electro-Metrics	Biconicalog Periodic	151	06-May-12			
WRLE02674	85662A	Hewlett-Packard	Analyzer Display	2050A02007	07-Dec-12			
WRLE02690	8568B	Hewlett-Packard	Spectrum Analyzer	2430A00930	07-Dec-12			
WRLE02681	85650A	Hewlett-Packard	Quasi-Peak Adapter	2430A00562	24-May-12			
WRLE02670	8447D	Hewlett-Packard	Preamplifier	2443A03954	Code B 06-Feb-13			
WRLE10527	SL18B4020	Phase One Microwave	Preamplifier 1 – 18 GHz	0001	Code B 05-Jan-13			
WRLE03229	3115	Electro-Mechanics	Ridge Guide Antenna	2483	04-Aug-12			
		(EMCO)						
WRLE03935	F548B-1	Acronetics	1 – 2 GHz Bandpass Filter	010	Code B 06-Feb-13			
Cal Code B = Cali	bration verification	on performed internally.						

Test data No spurious emissions detected within 10 dB of the limit.



Receiver Radiated Emissions 30 - 9300 MHz FCC 15.109, IC RSS Gen Section 6

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 8.2.3, 8.2.4.

No receiver emissions were detected.

Test limits 15.109

Frequency	Field strength	Field strength	Measurement
(MHz)	(μV/m)	(dBμV/m)	distance (m)
30 – 88	100	40	3
88 – 216	150	43.5	3
216 – 960	200	46	3
Above 960	500	54	3

All measurements made at 3 meters. The emission limits shown in the above tables are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9-90 kHz, 110-490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated emission measurements are specified in this part, including average emission measurements below 1000 MHz, there also is a limit on the peak level of the radio frequency emissions. Unless otherwise specified, e.g., see §§ 15.250, 15.252, 15.255, and 15.509–15.519, the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees.

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

Test distance

■ - 3 meters

Test Fauinment

rest Equipine	rest Equipment							
TUV ID	Model	Manufacturer	Description	Serial	Cal Due			
WRLE03995	EM-6917B	Electro-Metrics	Biconicalog Periodic	151	06-May-12			
WRLE02674	85662A	Hewlett-Packard	Analyzer Display	2050A02007	07-Dec-12			
WRLE02690	8568B	Hewlett-Packard	Spectrum Analyzer	2430A00930	07-Dec-12			
WRLE02681	85650A	Hewlett-Packard	Quasi-Peak Adapter	2430A00562	24-May-12			
WRLE02670	8447D	Hewlett-Packard	Preamplifier	2443A03954	Code B 06-Feb-13			
WRLE10527	SL18B4020	Phase One Microwave	Preamplifier 1 – 18 GHz	0001	Code B 05-Jan-13			
WRLE03229	3115	Electro-Mechanics (EMCO)	Ridge Guide Antenna	2483	04-Aug-12			
WRLE03935 Cal Code B = Cali	F548B-1	Acronetics on performed internally.	1 – 2 GHz Bandpass Filter	010	Code B 06-Feb-13			

Test data

No receiver emissions were detected.

Test Report WC1202311.2 Rev A



Occupied bandwidth RSS-Gen 4.6.1

Test summary

The requirements are: ■ - MET □ - NOT MET

Test was performed in accordance with the article "The Measurement of Occupied Bandwidth" by Industry Canada's certification bureau.

Occupied bandwidth = 197.2 kHz

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

☐ - Wild River Lab Small Test Site (Open Area Test Site)

Test equipment

TUV ID.	Model Number	Manufacturer	Description	Serial Number	Cal Due
WRLE03371	E4440A	Agilent	Spectrum Analyzer	MY43362222	06-Sep-12
WRLE03995	EM-6917B	Electro-Metrics	Biconicalog Periodic	151	06-May-12
WRLE02670	8447D	Hewlett-Packard	Preamplifier	2443A03954	Code B 06-Feb-

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Test limit

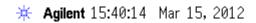
No limit specified

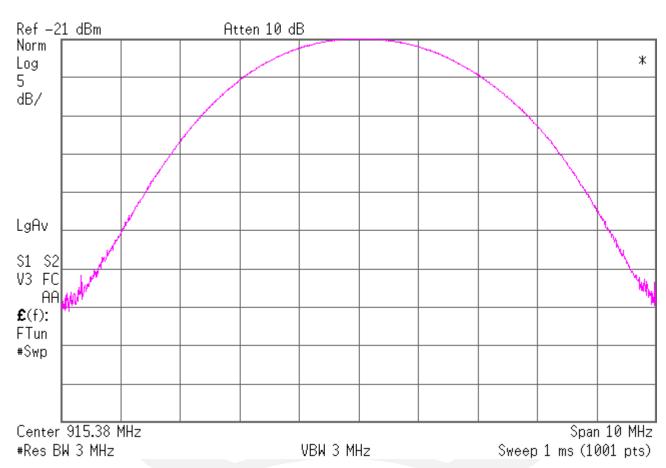
Test data

See following pages



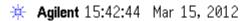
99% Occupied bandwidth 1 of 2

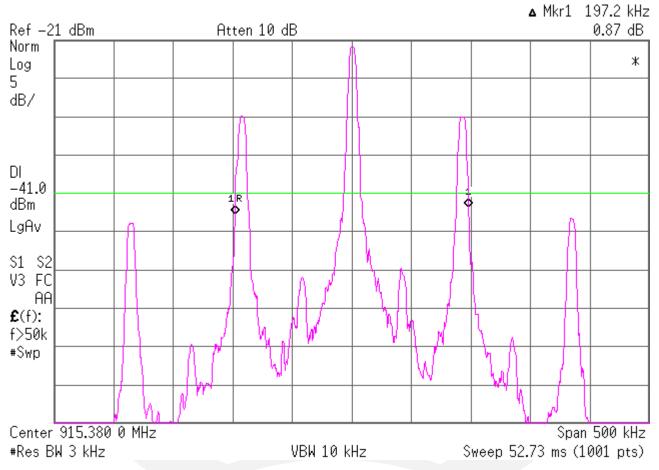






99% Occupied bandwidth 2 of 2







Conducted Emissions - AC Power Lines FCC 15.207(a), IC RSS-Gen 7.2.4

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 7.2

Test location

- - Wild River Lab Large Test Site (Open Area Test Site)
- □ Wild River Lab Small Test Site (Open Area Test Site)

Tost aquinment used:

rest equipin	ent useu.						
TUV ID Model Manufacturer			Description	Serial	Cal Due		
OWLE02078	3825/2	Electro-Mechanics (EMCO)	50 Ω LISN	1326	Code B 20-Jul-12		
WRLE02534	ESHS-20	Rohde & Schwarz	EMI Receiver 9kHz-30MHz	837055/003	15-Jun-12		
Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.							

Test limits, dB_µV

Frequncy	dBuV	dBuV
(MHz)	Quasi Peak	Average
0.15 - 0.5	66 - 56*	56 - 46*
0.5 - 5	56	46
5 - 30	60	50

^{*}Decreases with the logarithm of the frequency

Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT are measured in the frequency range of 150 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth (9 kHz resolution bandwidth) and quasi-peak/average detection, and a Line Impedance Stabilization Network (LISN), with 50 Ω /50 μ H (CISPR 16) characteristics. Table top equipment is placed on a non-conducting table 80 centimeters above the floor and is positioned 40 centimeters from the vertical ground plane (wall) of the screen room. In some cases, a pre-scan using a spectrum analyzer is initially performed on the units comprising the system under test to locate the highest emissions. Conducted emissions were measured on the Communication Link Controller, which powers the transceiver over Ethernet.

Test data

Battery operated implantable – not applicable

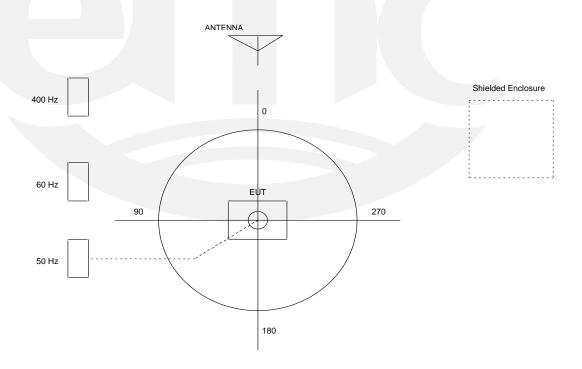


TEST SETUP FOR EMISSIONS TESTING

WILD RIVER LAB Large Test Site

Notes:

- 1. Items shown in dotted lines are located on the floor below the test area. It is 5 meters vertically from the ground floor to the test area.
- 2. 50 Hz, 60 Hz, and 400 Hz are power panels for alternating current.
- The antenna may be positioned horizontally 3, 10 or 30 meters from the center of the turntable.
- The circle is a 6.7 meter diameter turntable.
- A ground plane is in the plane of this sheet.
- The test sample is shown in the azimuthal position representing zero degrees.





Test-setup photo(s): Radiated emissions





Test-setup photo(s): Conducted Emissions, AC lines, 150 kHz - 30 MHz

Not applicable





Equipment Under Test (EUT) Test Operation Mode:

4. F
The device under test was operated under the following conditions during testing :
□ - Standby
□ - Test program (H - Pattern)
□ - Test program (color bar)
□ - Test program (customer specific)
□ - Practice operation
■ - Normal operating mode – implantable transmitter tested in body simulator.
Configuration of the device under test:
■ - See Appendix A and test setup photos
□ - See Product Information Form(s) in Appendix B



DEVIATIONS FROM STANDARD: None.								
GENERAL REMAR None	RKS:							
Modifications required a ■ None □ As indicated on the								
■ Implantable transmi	Test Specification Deviations: Additions to or Exclusions from: Implantable transmitter tested in body simulator. □ As indicated in the Test Plan							
- met and the device	ording to the technical regulations an under test does fulfill the general ap evice under test does not fulfill the g	oproval requirements.						
EUT Received Date:	12 March 2012							
Condition of EUT:	Normal							
Testing Start Date:	12 March 2012							
Testing End Date:	15 March 2012							
TÜV SÜD AMERIC	A INC							
Tested by:		Approved by:						
I Jakubaur	Li.	Joel T. Sohneisen						
Greg Jakubowski Senior EMC Technician	า	Joel T Schneider Senior EMC Engineer						



Appendix A

Constructional Data Form





PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.

NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Company:	Data Sciences Internation	nal		
Address:	119-14 th Street			
	St. Paul, MN 55112			
Contact:	John Yates	Po	sition:	Principal Electrical Engineer
Phone:	651-414-5366	Fa	x:	
E-mail Address:	jyates@datasci.com			
General Equipment	Description NOTE: This	information will b	e input in	to your test report as shown below.
EUT Description	Data Acquisition System		,	,
EUT Name	TruSense			
Model No.:	Multiple (recorded on da	ta sheet) Se	rial No.:	Multiple (recorded on datasheet)
Product Options:		_		
Configurations to be		.C (product) cor		
	Switch+Rou	ter+APR+Com	puter+Mo	onitor (OTS)
Equipment Modifica	ation (If applicable, indicate n	nodifications sinc	e EUT was	last tested. If modifications are made
	mit revised TP/CDF after testin			
Modifications since la	ast test:			
Modifications made of	during test:			
Total Objection (a)				
		FCC:	g the appli Cla	ss A B Part
Std:	04/108/EC (EMC)	☐ FCC.	Cla	~
	ve 89/392/EEC (EMC)	_ ☐ VOOI:	Cla	
Std:	,	🔲 Canada	: Cla	ss 🗍 A 🗍 B
	virective 93/42/EEC (EMC)	Australia	a: Cla	ss 🗌 A 🗌 B
Std: Vehicle Directive	- 2004/104/EC (EMC)	_ =	ctive *20	09/64/EC (EMC)
☐ Other Vehicle St	` ,			55,5
—	Guidance for Premarket			
	Guidance for Premarket			



Third Party Certification (contact TÜV for quote), if applicable (*Signature on last page required).
☐ Attestation of Compliance (AoC)*	☐ EMC Certification (used with Octagon Mark)*
	Il aspects of the essential requirements were assessed
Protection Class (Req'd for AoC, SoC, EMC Cert. N// (Press F1 when field is selected to show additional information on P	
FCC / TCB Certification	Taiwan Certification
☐ Industry Canada / FCB Certification	
e-Mark Certification	
Attendance	
Test will be: Attended by the customer	☐ Unattended by the customer
Failure - Complete this section if testing will no	ot be attended by the customer.
If a failure occurs, TÜV SÜD America should:	
☐ Call contact listed above, if not available then	stop testing. (After hrs phone):
Continue testing to complete test series.	
Continue testing to define corrective action.	
Stop testing.	
EUT Specifications and Requirements	
Length: Width:	Height: Weight:
Power Requirements	
Regulations require testing to be performed at typical pow European power is typically 230 VAC 50 Hz or 400 VAC 50 H	
	I, make sure battery life is sufficient to complete testing.)
\	,
# of Phases:	
Current Current	4 1 0)
(Amps/phase(max)): (Amps/pha	ase(nominal)):
Other	
Other Special Requirements	
Typical Installation and/or Operating Environment	ent
(ie. Hospital, Small Business, Industrial/Factory,	
•	
EUT Power Cable	
Permanent OR Removable	Length (in meters):
Shielded OR Unshielded	Lengui (iii iiieters).
Not Applicable	



EUT Interfac	e Po	orts				s			T	1		1		
			Du Te	ring est			,	Shielding				sted rs)	ple	ent
Туре	Analog	Digital	Active	Passive	Qty	Yes	o N	Туре	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
EXAMPLE: RS232		×	×		2	×		Foil over braid	Coaxial	Metallized 9- pin D-Sub	Characteristic Impedance	6	×	
THE COLUMN TO TH								r on over praid	Сосили			<u> </u>		

Form



EUT Software.			
Revision Level:			
Description:			
Equipment Under Test (EUT) Oper It is recommended the equipment be tested w peripherals requires that a simple program ge firmware, and PLD algorithms used in the equipment testing. Consult with your TÜV Product Service	while operating in a typical op enerate a complete line of upposition in the complete line of upposition in the contract of th	eration mode. FCC testin per case H's. Provide a g es as described above, w	g of personal computers and/or eneral description of all software, ith the revision level used during
1.			
2.			
3.			
ა.			
Equipment Under Test (EUT) Systems For FCC & Taiwan testing a minimum configu			
Description	Model #	Serial #	FCC ID #



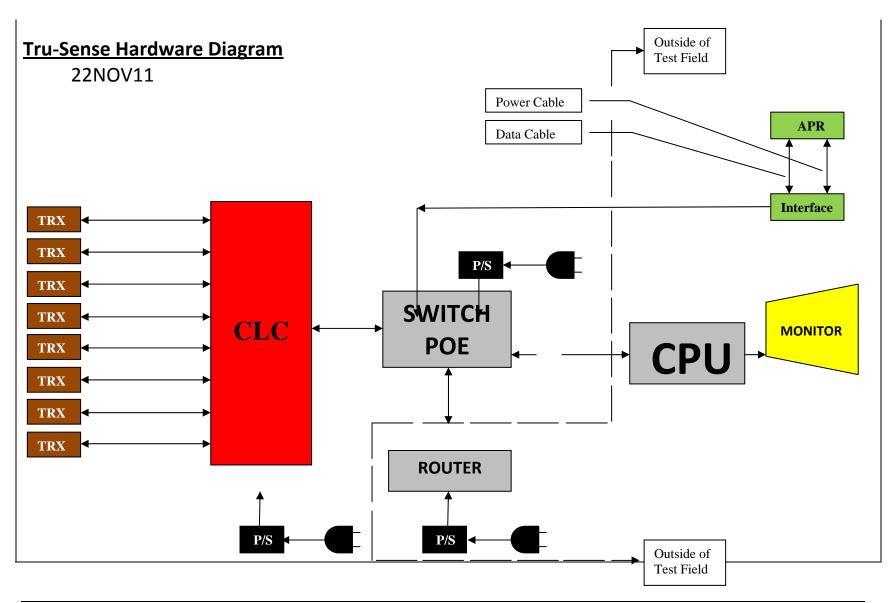
Support Equ This information	ipment Lis is required for F	st and describe all sup	pport equipme	ent which is not pa	art of the EUT. (i.e. peripherals, simulators, etc))
Description		Model #		Serial #	FCC ID #	
Oscillator Fr	oguancias					
Oscillator Fi	equencies	Derived				_
Manufacturer	Frequency	Frequency	Compone	nt # / Location	Description of Use	
Power Suppl	ly Model	!# Seria	1.4	T		
wanuracturer	iviodei	# Seria	<i>I #</i> -	Type		
				Linear	d-mode: (Frequency) Other:	_
				Switche	d-mode: (Frequency)	_
				Linear	Other:	
		<u>'</u>				
Power Line F	ilters					
Manufacturer		Model #		Location in El	JT	



Critical EMI Com	ponents (Capacitors, ferr	ites, etc.)		
Description	Manufacturer	Part # or Value	Qty	Component # / Location
	L		I	
MC Critical Deta	il Describe other EMC Design	details used to reduce high	gh frequency	/ noise.
	NAMES BELOW (INSERT gnature Required if a Thi			
0 11 11 11 11				
Customer author according to this	orization to perform tests is test plan.	Date		
Test Plan/CDF	Prepared By (please print)	 Date		

America

EMC Block Diagram Form



Form



EMC Block Diagram Form

Authorization Signatures		
Customer authorization to perform tests according to this test plan.	Date	
Test Plan/CDF Prepared By (please print)		